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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/598,989 | 09/18/2006 | Alexander Thomas Jacobs | X16606 | 3016 |
| 25885 7590 03/02/2010 ELI LILLY & COMPANY PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288 | | | | |
| EXAMINER FLICK, JASON E | | | | |
| ART UNIT 3763 | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary

Application No.

10/598,989

Applicant(s)

JACOBS ET AL.

Examiner

JASON FLICK

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 16 and 17 is/are rejected.
- 7) ☒ Claim(s) 5-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date 05/21/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

35 USC § 112, 6th Paragraph – Means-plus-function Interpretation

1. The examiner would like to indicate that claim 11 has been interpreted as applicant evoking 35 U.S.C. 112, 6th paragraph. In this light, the examiner has indicated (as noted below) claim 11 as allowable subject matter based upon applicant's disclosure of means for preventing an injection until the plunger has been manually shifted to said proximal position that corresponds to a fully cocked position, as indicated in the disclosure as a "partial-cocking-preventing mechanism." The examiner interprets this as separate and distinct from applicant's "means for preventing use of the apparatus after a particular number of doses", "prevention of use after a final injection", or any other prevention means disclosed.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 4 indicates the drive member rack engaging teeth are associated with the first pinion, which is inconsistent with claim 1. For the purposes of examination, the examiner interprets the structures of claim 4 as disclosed in claim 1.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4 and 16 rejected under 35 U.S.C. 102(b) as being anticipated by Muhlbauer (USPN 5,782,633).

7. [Claims 1-3 and 16] Muhlbauer teaches a medication dispensing apparatus comprising: a housing (figure 1, item 1); a drive member within said housing and movable in a distal direction (figure 1, item 5); a fluid container defining a medicine-filled reservoir with a movable piston at one end and an outlet at the other end, said piston engageable by said drive member to be advanced toward said outlet when said drive member is moved distally (figure 1, item 4); a plunger movable relative to said housing from a distal position to a proximal position, said plunger manually pushable relative to said housing in the distal direction to be shifted from said proximal position to said distal position (figure 1, item 11); means for interconnecting said drive member and said plunger to convert motion of said plunger from said proximal position to said distal position into a lesser amount of motion of said drive member in said distal direction (column 2, lines 23-34), said interconnecting means including a gear set (figure 1, items 6-10) including a first pinion (figure 1, item 8) in meshed engagement with a rack of said plunger (figure 1, item 9) and a second pinion (figure 1, item 7) in meshed engagement with a rack of said drive member (figure 1, item 6), wherein said first and second pinion

are corotatable and coaxially arranged within said housing; and characterized in that at least a portion of said drive member extends through an opening through at least one of said first and second pinions (figure 1); wherein said first pinion (figure 1, item 8) comprises said opening, wherein plunger rack engaging teeth of said first pinion are coplanar with said at least a portion of said drive member (figure 1, items 5 and 6) extending through said opening, whereby said rack engaging teeth do not extend continuously around said first pinion (figure 1); and wherein an axis of rolling rotation of said first pinion extends through said opening and is oriented generally perpendicular to said at least a portion of said drive member extending through said opening (figure 1).

8. [Claim 4] Muhlbauer teaches the limitations of claim 1, upon which claim 4 depends. In addition, Muhlbauer discloses the plunger rack engaging teeth are arranged with a larger pitch diameter than the pitch diameter of the drive member engaging teeth (column 3, lines 9-15). Muhlbauer indicates the first pinion has a ratio to the second pinion of 3:1. Therefore, the corresponding pitch diameters of the rack engaging teeth would have to have a corresponding relationship.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Muhlbauer (USPN 5,782,633).

13. [Claim 17] Muhlbauer teaches the limitations of claim 1, upon which claim 17 depends. Muhlbauer does not explicitly disclose the second pinion comprises a pair of mirror image pinions or that the first and second pinions comprise a one-piece construction. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a pair of pinions, rather than a single pinion, since it has been held that mere duplication of the essential working parts of a device involves

only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a one-piece construction for the pinions, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1993).

Allowable Subject Matter

14. Claims 5-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, as well as correcting the rejection under 35 U.S.C. 112, second paragraph.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON FLICK whose telephone number is (571)270-7024. The examiner can normally be reached on Monday through Thursday, 7:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F./
Examiner, Art Unit 3763
02/25/2010

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763